

REMARKS

Reconsideration of the rejections set forth in the Office Action mailed on January 30, 2006, is respectfully requested. Claims 1, 5-9, 17-20, 22-25, and 27 have been amended. Claims 2-4, 15-16, 26, and 28-40 have been cancelled. Support for these amendments can be found in the specification at, e.g., page 8, line 14 - page 11, line 18. Therefore, these amendments have been made without the addition of new matter.

Finality of the Office Action

Applicants note that the Examiner indicated that this Office Action was “final” in the Office Action Summary. Applicants believe that this box was marked in error as this is the first office action received after the Amendment and Response to Restriction Requirement mailed November 3, 2005. Therefore, Applicants respectfully request withdrawal of the finality of the office action.

Information Disclosure Statement

Applicants have submitted herewith a Supplemental Information Disclosure Statement listing the non-patent literature previously cited in the Information Disclosure Statement mailed on February 11, 2004, along with copies of the non-patent literature. Applicants respectfully request that the Examiner return the initialed PTO/SB/08A with the next communication.

Drawings

Applicants have submitted herewith formal drawings. Applicants believe that these formal drawings will address the Examiner's concerns.

Sequence Rules Compliance

Applicants have submitted herewith a sequence listing (both paper copy and in computer-readable form). The specification has also been amended to include the SEQ ID NOS.

Specification

The Examiner has objected to the specification for various informalities. Various paragraphs have been amended to correct typographical errors. Replacement tables have been included where some of the words were difficult to read. Additionally, SEQ ID NOS. have been added to the tables that contain nucleotide sequences.

Claim Objections

Claim 1 was objected to for the following informalities: (1) "patient sample nucleic acid" and (2) "hybridization." Applicants have amended claim 1 to recite "a patient sample nucleic acid" and have deleted the word "hybridization."

Claims 3 and 4 were cancelled. Therefore, the rejections to these claims are now moot. Claim 5 was amended to recite "The method"

Claim 40 has been cancelled. Therefore, the rejection to this claim is now moot.

35 U.S.C. § 112

Claims 1 and 24-26 were rejected under 35 U.S.C. 112, first paragraph, because the specification allegedly does not reasonably provide enablement for using the method in claim 1 for detecting a genetic disease such as cystic fibrosis, Beta-Thalassemia, and others. Claim 26 has been cancelled. Therefore, the rejections to claim 26 are now moot. Applicants have amended claim 1 to specify a “method for detecting a genetic marker” by “detecting the presence of the discriminator.” Furthermore, claim 24 has been amended to specify that the “genetic marker is indicative of a genetic disease.” Claim 25 specifies that the genetic disease is cystic fibrosis. Applicants respectfully assert that there is ample support in the specification at, e.g., page 9, line 20 - page 11, line 18, page 45, line 22 - page 66, line 16, and Tables 11 and 12. Therefore, Applicants respectfully request withdrawal of the rejections and reconsideration of the claims as amended.

Claims 1-9, 15-20, and 22-40 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to point out and distinctly claim the subject matter that Applicant regards as the invention.

In particular, claims 1, 28, 34, and 40 were rejected as allegedly vague and indefinite. Claims 28, 34, and 40 have been cancelled. Therefore, the rejections to these claims are now moot. Claim 1 has been amended to include a step of “detecting the genetic marker by detecting the presence of the discriminator.”

Claim 15 was rejected as allegedly vague and indefinite. Claim 15 has been cancelled. Therefore, the rejection to this claim is now moot.

Claim 23 was rejected as allegedly vague and indefinite because there is no word “color” in claim 1. Claim 23 has been amended and no longer contains the reference to “color.”

Claim 28 was rejected as allegedly vague and indefinite. Claim 28 has been cancelled. Therefore, the rejection to this claim is now moot.

Art Rejections

Claims 1-9, 15, 17-20, 22-24, and 26-40 have been rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Nerenberg et al. (USP 6,468,742). Claim 16 was rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Nerenberg et al., further in view of Arnold et al. (USP 6,410,231). Claim 25 was rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Nerenberg et al. in view of Song et al. (USP 6,451,526).

The Examiner has taken the position that “the at least one stabilizer oligonucleotide” described in Nerenberg is a “blocker ... selected for particular loci,” as previously required by claim 1. Applicants respectfully assert that Nerenberg does not teach or suggest “*at least one blocker that is complementary to at least one loci of the multiple loci contained in the patient sample nucleic acid,*” as required in amended claim 1. Although the stabilizer described in Nerenberg is complementary to a portion of the amplification product, it is not complementary to “at least one loci of the multiple loci contained in the patient sample nucleic acid.” As stated in Nerenberg, “[t]he stabilizer oligomer 33 is generally a 30-mer that is 100% complementary to both wild type and mutant alleles. This stabilizer directly abuts the polymorphism site on the target amplicon such that when a perfectly matched mutant reporter 34 or wild-type 35 is added to the system, base-stacking will be present.” (emphasis added, Col. 16, lines 30-36). Because the stabilizer “directly abuts” the loci, it is not complementary to the loci, but rather is complementary to a sequence near the loci. Additionally, because the stabilizer is “100%

complementary to both wild type and mutant alleles,” the stabilizer must not be hybridizing with the portion of the amplification product that contains the loci (i.e., the polymorphism that makes the mutant different from the wild type). As stated previously, the stabilizer is hybridizing with a portion of the amplification products that is common to both.

Claims 5-9, 17-20, 22-25, and 27 depend from claim 1 and are patentably distinct for the same reasons as applicable to claim 1. Therefore, Applicants respectfully request withdrawal of the rejections and reconsideration of the claims as amended.

Favorable action on the merits of the claims is therefore earnestly solicited. If any issues remain, please contact Applicant’s undersigned representative at (949) 760-9600. The Commissioner is hereby authorized to charge any additional fees that may be required to Deposit Account No. 50-2862.

Respectfully submitted,
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